REMARKS

Claims 1-12 are presently pending in this application. Claims 1, 11 and 12 are herein amended and support can be found throughout the specification and claims as filed. Specifically, support for claim 1 can be found at least at page 3, lines 14-17, page 55, lines 4-6 while support for claims 11 and 12 can be found at least at page 6, lines 24-26. *No new matter has been added.* Upon entrance of this amendment, claims 1-12 will remain pending.

Preliminary Matters

As a preliminary matter, Applicant has amended claim 1 such that the phrase "pharmaceutically acceptable form" has been replaced by the phrase "pharmaceutically acceptable salt." Claim 1 is further amended to recite "wherein in the crystallisation induced dynamic resolution step, a desired enantiomer is preferentially crystallized." Claims 11 and 12 are amended to recite "wherein R^2 is $-(CH_2)_m-R^f$ wherein m is 0-3 and R^f is selected from the group consisting of -O-(C_{1-6} alkyl), p-methoxyphenyl-, -OC(O)-(C_{1-6} alkyl), aryl, heteroaryl, carbocyclyl and heterocyclyl". Applicant notes that these amendments are made solely for the purpose of expediting prosecution and should not be construed as acquiescence to any outstanding objection/rejection raised by the Examiner.

35 U.S.C. § 112, ¶ 2 Rejection of Claims 1-10

Claims 1-10 stand rejected under 35 U.S.C. § 112, 2nd paragraph on the basis that they are indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Particularly, it is asserted that the terms (i) benzodiazepine derivative, (ii) amino protecting group, (iv) pharmaceutically acceptable form and (v) crystallization induced dynamic resolution render the claims unclear. It is also asserted that (iii) the claims are not clearly written as the process results in a racemic mixture. Applicant respectfully disagrees with the basis of this rejection.

Applicants respectfully submit that it is permissible to "use...alternative expressions...or any style of expression or format of claim which makes clear the boundaries of the subject matter for which protection is sought." *See* MPEP 2173.01. As recited in present claims 1-10, a benzodiazepine derivative is an alternate expression of the compound which is fully defined, as noted by the Examiner, by the structural formulas and definitions of the variables. Accordingly, one of ordinary skill in the art would understand what the metes and bounds of a derivative are, as recited in these claims.

Applicants respectfully submit that one of ordinary skill in the art would understand the metes and bounds defined by the term "amino protecting group". Nonetheless, Applicant respectfully calls the Examiner's attention to page 6, lines 5-26 wherein Applicants have fully described what they regard as an amino protecting group. For example, though not exhaustive, an amino protecting group includes $-(CH_2)_m-R'$ wherein m is 0-3 and R' is selected from the group consisting of -O-(C_{1-6} alkyl), p-methoxyphenyl-, -C(O)O-(C_{1-6} alkyl), -OC(O)-(C_{1-6} alkyl), aryl, heteroaryl, carbocyclyl and heterocyclyl. Accordingly, Applicants respectfully submit that the term amino protecting group is not indefinite.

At least in view of the amendment made to claim 1, Applicants further submit that the claims are clearly written. As amended, claim 1 now recites that in the crystallisation induced dynamic resolution step a desired enantiomer is preferentially crystallized. As such, Applicants submit that the claims are clearly written.

As amended, claim 1 now recites a "pharmaceutically acceptable salt" instead of a "pharmaceutically acceptable form". Applicants respectfully submit that one of ordinary skill in the art would understand the metes and bounds of what Applicants regard as their invention. Applicants therefore submit that the rejection based on the term "pharmaceutically acceptable form" is rendered moot.

The Examiner requests disclosure of the reagents used in step (a) of the process in claims 1-10. Applicants respectfully submit that in view of the amendment to claim 1 to recite that "...in the crystallisation induced dynamic resolution step, a desired enantiomer is preferentially

crystallized," the rejection of claims 1-10 for failure to recite essential method steps is herein rendered moot. Particularly, Applicants note that the reagent is the racemic mixture of formula (IIa) and that the final product is an enantiomer that is preferentially crystallized by the crystallization induced dynamic resolution step.

In view of these arguments and amendments, Applicants respectfully request reconsideration and withdrawal of this rejection.

35 U.S.C. § 102(b) Rejection of Claims 11 and 12

Claims 11 and 12 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Rawson *et al.* (Bioorganic & Medicinal Chemistry Letters (1995), 5(13), 1335-8). Specifically, it is asserted that claims 11 and 12 read on compounds III and IV of Rawson *et al.* Applicants respectfully disagree.

At least in view of the amendments made herein to claims 11 and 12, Applicants submit that compounds III and IV do not fall within the scope of claims 11 or 12. Specifically, Applicants note that claims 11 and 12 recite that "R^2 is -$(CH_2)_m$-R' wherein m is 0-3 and R' is selected from the group consisting of -O-(C_{1-6} alkyl), p-methoxyphenyl-, -OC(O)-(C_{1-6} alkyl), aryl, heteroaryl, carbocyclyl and heterocyclyl". However, both compounds III and IV contain a methyl acetate group at the position corresponding to the amino protecting group (R^2) of the present invention. Accordingly, Rawson *et al.* does not disclose every element of claims 11 and 12 and therefore does not anticipate claim 11 or 12. Applicants therefore respectfully request reconsideration and withdrawal of this rejection.

35 U.S.C. § 103(a) Rejection of Claims 1-10

Claims 1-10 stand rejection under 35 U.S.C. § 103(a) as being obvious in view of Rawson *et al.* (Bioorganic & Medicinal Chemistry Letters (1995), 5(13), 1335-8). Applicants respectfully disagree.

Applicants note that claims 1-10 include a step (b) which requires the deprotection of the benzodiazepine derivative. Rawson *et al.* fails to teach or suggest this method step. Accordingly, Rawson *et al.* does not render the claimed invention obvious. At least in view of this argument, Applicants respectfully request reconsideration and withdrawal of this rejection.

If there are any questions regarding the proposed amendments to the application, we invite the Examiner to call Applicant's representative at the telephone number below.

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